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(Original Signature of Member)

107TH CONGRESS
1ST SESSION

H. R. _____

IN THE HOUSE OF REPRESENTATIVES

Ms. DUNN introduced the following bill; which was referred to the Committee
on _____

A BILL

To amend title XVIII of the Social Security Act to establish
procedures for determining payment amounts for new
clinical diagnostic laboratory tests for which payment
is made under the medicare program.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Medicare Patient Ac-
5 cess to Preventive and Diagnostic Tests Act”.

1 **SEC. 2. CODING AND PAYMENT PROCEDURES FOR NEW**
2 **CLINICAL DIAGNOSTIC LABORATORY TESTS**
3 **UNDER MEDICARE.**

4 (a) DETERMINING PAYMENT BASIS FOR NEW LAB
5 TESTS.—Section 1833(h) of the Social Security Act (42
6 U.S.C. 1395l(h)) is amended by adding at the end the fol-
7 lowing:

8 “(9)(A) The Secretary shall establish proce-
9 dures for determining the basis for, and amount of,
10 payment under this subsection for any clinical diag-
11 nostic laboratory test with respect to which a new or
12 substantially revised HCPCS code is assigned on or
13 after January 1, 2002 (hereinafter in this paragraph
14 and paragraph (10) referred to as ‘new tests’). Such
15 procedures shall provide that—

16 “(i) the payment amount for such a test
17 will be established only on—

18 “(I) the basis described in paragraph
19 (10)(A); or

20 “(II) the basis described in paragraph
21 (10)(B); and

22 “(ii) the Secretary will determine whether
23 the payment amount for such a test is estab-
24 lished on the basis described in paragraph
25 (10)(A) or the basis described in paragraph
26 (10)(B) only after the process described in sub-

1 paragraph (B) has been completed with respect
2 to such test.

3 “(B) Determinations under subparagraph
4 (A)(ii) shall be made only after the Secretary—

5 “(i) makes available to the public (through
6 an Internet site and other appropriate mecha-
7 nisms) a list that includes any such test for
8 which establishment of a payment amount
9 under paragraph (10) is being considered for a
10 year;

11 “(ii) on the same day such list is made
12 available, causes to have published in the Fed-
13 eral Register notice of a meeting to receive
14 comments and recommendations from the pub-
15 lic on the appropriate basis under paragraph
16 (10) for establishing payment amounts for the
17 tests on such list;

18 “(iii) not less than 30 days after publica-
19 tion of such notice, convenes a meeting to re-
20 ceive such comments and recommendations,
21 with such meeting—

22 “(I) including representatives of all
23 entities within the Health Care Financing
24 Administration (hereinafter in this para-
25 graph referred to as ‘HCFA’) that will be

1 involved in determining the basis on which
2 payment amounts will be established for
3 such tests under paragraph (10) and im-
4 plementing such determinations;

5 “(II) encouraging the participation of
6 interested parties, including beneficiaries,
7 device manufacturers, clinical laboratories,
8 laboratory professionals, pathologists, and
9 prescribing physicians, through outreach
10 activities; and

11 “(III) affording opportunities for
12 interactive dialogue between representa-
13 tives of HCFA and the public;

14 “(iv) makes minutes of such meeting avail-
15 able to the public (through an Internet site and
16 other appropriate mechanisms) not later than
17 15 calendar days after such meeting;

18 “(v) taking into account the comments and
19 recommendations received at such meeting, de-
20 velops and makes available to the public
21 (through an Internet site and other appropriate
22 mechanisms) a list of proposed determinations
23 with respect to the appropriate basis for estab-
24 lishing a payment amount under paragraph
25 (10) for each such code, together with an expla-

1 nation of the reasons for each such determina-
2 tion, and the data on which the determination
3 is based;

4 “(vi) on the same day such list is made
5 available, causes to have published in the Fed-
6 eral Register notice of a public meeting to re-
7 ceive comments and recommendations from the
8 public on the proposed determinations;

9 “(vii) not later than August 1 of each year,
10 but at least 30 days after publication of such
11 notice, convenes a meeting to receive such com-
12 ments and recommendations, with such meeting
13 being conducted in the same manner as the
14 meeting under clause (iii);

15 “(viii) makes a transcript of such meeting
16 available to the public (through an Internet site
17 and other appropriate mechanisms) as soon as
18 is practicable after such meeting; and

19 “(ix) taking into account the comments
20 and recommendations received at such meeting,
21 develops and makes available to the public
22 (through an Internet site and other appropriate
23 mechanisms) a list of final determinations of
24 whether the payment amount for such tests will
25 be determined on the basis described in para-

1 graph (10)(A) or the basis described in para-
2 graph (10)(B), together with the rationale for
3 each such determination, the data on which the
4 determination is based, and responses to com-
5 ments and suggestions received from the public.

6 “(C) Under the procedures established pursuant
7 to subparagraph (A), the Secretary shall—

8 “(i) identify the rules and assumptions to
9 be applied by the Secretary in considering and
10 making determinations of whether the payment
11 amount for a new test should be established on
12 the basis described in paragraph (10)(A) or the
13 basis described in paragraph (10)(B);

14 “(ii) make available to the public the data
15 (other than proprietary data) considered in
16 making such determinations; and

17 “(iii) provide for a mechanism under
18 which—

19 “(I) an interested party may request
20 an administrative review of an adverse de-
21 termination;

22 “(II) upon the request of an inter-
23 ested party, an administrative review is
24 conducted with respect to an adverse deter-
25 mination; and

1 “(III) such determination is revised,
2 as necessary, to reflect the results of such
3 review.

4 “(D) For purposes of this paragraph and
5 paragraph (10)—

6 “(i) the term ‘HCPCS’ refers to the
7 Health Care Financing Administration
8 Common Procedure Coding System; and

9 “(ii) a code shall be considered to be
10 ‘substantially revised’ if there is a sub-
11 stantive change to the definition of the test
12 or procedure to which the code applies
13 (such as a new analyte or a new method-
14 ology for measuring an existing analyte-
15 specific test).

16 “(10)(A) Notwithstanding paragraphs (1), (2),
17 and (4), if a new test is clinically similar to a test
18 for which a fee schedule amount has been estab-
19 lished under paragraph (5), the Secretary shall pay
20 the same fee schedule amount for the new test. In
21 determining whether tests are clinically similar for
22 purposes of this paragraph, the Secretary may not
23 take into account economic factors.

24 “(B)(i) Notwithstanding paragraphs (1), (2),
25 (4), and (5), if a new test is not clinically similar to

1 a test for which a fee schedule has been established
2 under paragraph (5), payment under this subsection
3 for such test shall be made on the basis of the lesser
4 of—

5 “(I) the actual charge for the test; or

6 “(II) an amount equal to 60 percent (or in
7 the case of a test performed by a qualified hos-
8 pital (as defined in paragraph (1)(D)) for out-
9 patients of such hospital, 62 percent) of the
10 prevailing charge level determined pursuant to
11 the third and fourth sentences of section
12 1842(b)(3) for the test for a locality or area for
13 the year (determined without regard to the year
14 referred to in paragraph (2)(A)(i), or any na-
15 tional limitation amount under paragraph
16 (4)(B), and adjusted annually by the percent-
17 age increase or decrease under paragraph
18 (2)(A)(i));

19 until the beginning of the third full calendar year
20 that begins on or after the date on which an
21 HCPCS code is first assigned with respect to such
22 test, or, if later, the beginning of the first calendar
23 year that begins on or after the date on which the
24 Secretary determines that there are sufficient claims

1 data to establish a fee schedule amount pursuant to
2 clause (ii).

3 “(ii) Notwithstanding paragraphs (2) and (4),
4 and (5), the fee schedule amount for a clinical diag-
5 nostic laboratory test described in clause (i) that is
6 performed—

7 “(I) during the first calendar year after
8 clause (i) ceases to apply to such test, shall be
9 an amount equal to the national limitation
10 amount that the Secretary determines (con-
11 sistent with clause (iii)) would have applied to
12 such test under paragraph (4)(B)(viii) during
13 the preceding calendar year, adjusted by the
14 percentage increase or decrease determined
15 under paragraph (2)(A)(i) for such first cal-
16 endar year; and

17 “(II) during a subsequent year, is the fee
18 schedule amount determined under this clause
19 for the preceding year, adjusted by the percent-
20 age increase or decrease that applies under
21 paragraph (5) (A) for such year.

22 “(iii) For purposes of clause (ii)(I), the national
23 limitation amount for a test shall be set at 100 per-
24 cent of the median of the payment amounts deter-
25 mined under clause (ii)(I) for all payment localities

1 or areas for the last calendar year for which pay-
2 ment for such test was determined under clause (i).

3 “(iv) Nothing in clause (ii) shall be construed
4 as prohibiting the Secretary from applying (or au-
5 thorizing the application of) the comparability provi-
6 sions of the first sentence of such section 1842(b)(3)
7 with respect to amounts determined under such
8 clause.”.

9 (b) ESTABLISHMENT OF NATIONAL FEE SCHEDULE
10 AMOUNTS.—

11 (1) IN GENERAL.—Section 1833(h) of the So-
12 cial Security Act, as amended by subsection (a), is
13 further amended—

14 (A) in paragraph (2), by striking “para-
15 graph (4)” and inserting in lieu thereof “para-
16 graphs (4), (5), and (10)”;

17 (B) in paragraph (4)(B)(viii), by inserting
18 “and before January 1, 2002,” after “Decem-
19 ber 31, 1997,”;

20 (C) by redesignating paragraphs (5), (6),
21 and (7), as paragraphs (6), (7), and (8), re-
22 spectively; and

23 (D) by inserting after paragraph (4) the
24 following:

1 “(5) Notwithstanding paragraphs (2) and (4),
2 the Secretary shall set the fee schedule amount for
3 a test (other than a test to which paragraph
4 (10)(B)) applies) at—

5 “(A) for tests performed during 2002, an
6 amount equal to the national limitation amount
7 for that test for 2001, and adjusted by the per-
8 centage increase or decrease determined under
9 paragraph (2)(A)(i) for such year; and

10 “(B) for tests performed during a year
11 after 2002, the amount determined under this
12 subparagraph for the preceding year, adjusted
13 by the percentage increase or decrease deter-
14 mined under paragraph (2)(A)(i) for such year.

15 (2) CONFORMING CHANGES.—Section 1833(a)
16 of the Social Security Act (42 U.S.C.1395l(a)) is
17 amended—

18 (A) in paragraph (1)(D)(i), by striking
19 “the limitation amount for that test determined
20 under subsection (h)(4)(B),”; and

21 (B) in paragraph (2)(D)(i), by striking
22 “the limitation amount for that test determined
23 under subsection (h)(4)(B),”.

24 (c) MECHANISM FOR REVIEW OF ADEQUACY OF PAY-
25 MENT AMOUNTS.—Section 1833(h) of the Social Security

1 Act, as amended by subsections (a) and (b), is further
2 amended by adding at the end the following:

3 “(11) The Secretary shall establish a mecha-
4 nism under which—

5 “(A) an interested party may request a
6 timely review of the adequacy of the existing
7 payment amount under this subsection fee for
8 a particular test; and

9 “(B) upon the receipt of such a request, a
10 timely review is carried out.”.

11 (d) USE OF INHERENT REASONABLENESS AUTHOR-
12 ITY.—Section 1842(b)(8) of the Social Security Act (42
13 U.S.C. 1395u(b)(8)) is amended by adding at the end the
14 following:

15 “(E)(i) The Secretary may not delegate
16 the authority to make determinations with re-
17 spect to clinical diagnostic laboratory tests
18 under this paragraph to a regional office of the
19 Health Care Financing Administration or to an
20 entity with a contract under subsection (a).

21 “(ii) In making determinations with re-
22 spect to clinical diagnostic laboratory tests
23 under this paragraph, the Secretary—

1 “(I) shall base such determinations on
2 data from affected payment localities and
3 all sites of care; and

4 “(II) may not use a methodology that
5 assigns undue weight to the prevailing
6 charge levels for any one type of entity
7 with a contract under subsection (a).

8 (e) PROHIBITION.—The Secretary may not assign a
9 code for a new clinical diagnostic laboratory test that dif-
10 fers from the code recommended by the American Medical
11 Association Common Procedure Terminology Editorial
12 Panel and results in lower payment than would be made
13 if the Secretary accepted such recommendation solely on
14 the basis that the test is a test that may be performed
15 by a laboratory with a certificate of waiver under section
16 353(d)(2) of the Public Health Service Act (42 U.S.C.
17 263a(d)(2)).

18 (f) EFFECTIVE DATES.—

19 (1) ESTABLISHMENT OF PROCEDURES.—The
20 Secretary of Health and Human Services shall es-
21 tablish the procedures required to implement para-
22 graphs (9), (10), and (11) of section 1833(h) of the
23 Social Security Act (42 U.S.C. 1395l(h)), as added
24 by this section, by not later than October 1, 2001.

1 (2) INHERENT REASONABLENESS; CODE AS-
2 SIGNMENT.—The amendments made by subsections
3 (d) and (e) shall apply to determinations made on or
4 after the date of the enactment of this Act.